Remarks

Reconsideration of this Application is respectfully requested.

I. Status of the Claims

Upon entry of the foregoing amendments, claims 1-13, 18-21, 26 and 29-38 are pending in the application, with claims 1, 2, 6, 7, and 26 being the independent claims. Claims 14-17, 27 and 28 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. New claims 39 and 40 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

II. Summary of the Office Action

In the Office Action dated December 3, 2001, the Examiner has made one objection to the specification and 10 rejections of the claims. Applicants respectfully offers the following remarks to overcome or traverse each element of the rejections in the Office Action.

III. Objection to the Specification

The Examiner takes the position that the first paragraph of the specification, containing the continuing data and claims of priority, is in an improper format. The specification has been amended using the format suggested by the Examiner.

Applicants respectfully request this objection be withdrawn.

IV. Rejections under 35 U.S.C. § 112

A. The Rejection of Claims 30 and 32

Claims 30 and 32 are rejected under 35 U.S.C. § 112, second paragraph, for being indefinite because they state that "the lipid or fatty acid is selected from the combination comprising . . .". The claims have been amended to replace the language "combination comprising" with the language "group consisting of."

Applicants respectfully request this rejection be withdrawn.

B. The Rejection of Claims 36-38

Claims 36-38 are rejected under 35 U.S.C. § 112, second paragraph, for being indefinite because they do not properly depend from claim 1. The claims have been amended to depend from claim 2.

Applicants respectfully request this rejection be withdrawn.

V. Other Matters

A. Obviousness-Type Double Patenting

Claims 1-13, 18-21 and 26-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,103,529.

First, it is not clear from the Office Action which claims from U.S. Patent No. 6,103,529 are relevant to the rejection of claims 1-13, 18-21 and 26-28 of the present

application. Clarification of this issue on the record is respectfully requested. Second, upon identification of patentable subject matter in the present application, Applicants will consider filing a terminal disclaimer. Therefore, it is respectfully requested that this rejection be held in abeyance until patentable subject matter is identified.

VI. Rejections under 35 U.S.C. § 102

A. Iscove et al.

Claims 2, 7, 10, 13, 20, 21, 26 and 28 are rejected under 35 U.S.C. § 102(b) as being anticipated by Iscove *et al.* Iscove *et al.* is alleged to disclose a culture medium for B lymphocytes that contains soybean lipids. Applicants respectfully traverse this rejection.

Claim 2 as currently presented recites that the non-animal or plant-derived lipid or fatty acid is derived from a source selected from the group consisting of bacteria, fungi, yeast, rice, potato, corn, and aloe vera. Independent claim 26 has also been amended to specify the source of the non-animal or plant-derived peptide, lipid or fatty acid. Claim 28 has been cancelled. Iscove *et al.* does not disclose non-animal or plant-derived lipids or fatty acids from any source other than soybean. Therefore, Iscove *et al.* does not anticipate independent claims 2 and 26 and hence cannot anticipate dependent claims 7, 10, 13, 20 and 21.

Applicants respectfully request this rejection be withdrawn.

B. Keay

Claims 1, 6, 12, 18, 19, 26, 27 and 33-35 are rejected under 35 U.S.C. § 102(b) as being anticipated by Keay. Keay allegedly discloses that soy peptone can be used to culture animal cells. Applicants respectfully traverse this rejection.

Claim 1 as currently presented recites that the non-animal or plant-derived peptide is derived from a source selected from the group consisting of fungi, yeast, rice, potato, corn, and aloe vera. Independent claim 26 has also been amended to specify the source of the non-animal or plant-derived peptide, lipid or fatty acid. Claim 27 has been cancelled. Keay does not disclose non-animal or plant-derived peptides from the sources recited in claim 1 as currently presented. Therefore, Keay does not anticipate the independent claims 1 and 26 and hence cannot anticipate dependent claims 6, 12, 18, 19 and 33-35.

Applicants respectfully request this rejection be withdrawn.

VII. Rejections under 35 U.S.C. § 103

A. Iscove et al. in view of the Gibco BRL Life Technologies 1993-1994 Catalogue and Reference Guide

Claims 2, 5, 7-9 and 29-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Iscove *et al.* in view of the Gibco BRL Life Technologies 1993-1994 Catalogue and Reference Guide. Applicants respectfully traverse this rejection.

In proceedings before the Patent and Trademark Office, the examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. See *In re Piasecki*, 223 USPQ 785, 787-88 (Fed. Cir. 1984). The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge

generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references in such a way as to produce the invention as claimed. *See In re Fine*, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). In the present case, the Examiner's burden has not been satisfied.

Claim 2 as currently presented recites that the non-animal or plant-derived lipid or fatty acid is derived from the group consisting of bacteria, fungi, yeast, rice, potato, corn, and aloe vera. As noted above, Iscove *et al.* does not disclose non-animal or plant-derived lipids or fatty acids obtained from any source other than soybean. Hence, Iscove *et al.* is seriously deficient as a primary reference upon which to base a *prima facie* case of obviousness. The Gibco Catalogue merely discloses that lipoic acid and myristate can be added to a culture medium. The Gibco Catalogue does not correct the deficiencies in the primary reference and, when combined with the primary reference, fails to establish a *prima facie* case of obviousness. Therefore, the claims are not unpatentable over Iscove *et al.* in view of the Gibco Catalogue.

Applicants respectfully request this rejection be withdrawn.

B. Iscove et al. in view of the CAPLUS abstract of Japanese Pat. No. 34002673

Claims 2, 7, 10 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Iscove *et al.* in view of the CAPLUS abstract of Japanese Pat. No. 34002673. Applicants respectfully traverse this rejection.

Claim 2 as currently presented recites that the non-animal or plant-derived lipid or fatty acid is derived from the group consisting of bacteria, fungi, yeast, rice, potato, corn, and aloe vera. As noted above, Iscove *et al.* does not disclose non-animal or plant-

derived lipids or fatty acids obtained from any source other than soybean. Hence, Iscove *et al.* is seriously deficient as a primary reference upon which to base a *prima facie* case of obviousness. The CAPLUS abstract of Japanese Pat. No. 34002673 discloses soybean stigmastanol. The CAPLUS abstract of Japanese Pat. No. 34002673 does not correct the deficiencies in the primary reference and, when combined with the primary reference, fails to establish a *prima facie* case of obviousness. Therefore, the claims are not unpatentable over Iscove *et al.* in view of the CAPLUS abstract of Japanese Pat. No. 34002673.

Applicants respectfully request this rejection be withdrawn.

C. Keay in view of the Gibco Catalogue

Claims 1 and 4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Keay in view of the Gibco Catalogue. Applicants respectfully traverse this rejection.

Claim 1 as currently presented recites that the non-animal or plant-derived peptide is derived from a source selected from the group consisting of fungi, yeast, rice, potato, corn, and aloe vera. As noted above, Keay does not disclose non-animal or plant-derived peptides from the sources recited in claim 1 as currently presented. Hence, Keay is seriously deficient as a primary reference upon which to base a *prima facie* case of obviousness. The Gibco Catalogue merely discloses that lipoic acid and myristate can be added to a culture medium. The Gibco Catalogue does not correct the deficiencies in the primary reference and, when combined with the primary reference, fails to establish a *prima facie* case of obviousness. Therefore, the claims are not unpatentable over Keay in view of the Gibco Catalogue.

Applicants respectfully request this rejection be withdrawn.

D. Iscove et al. in view of Keay

Claims 1 and 3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Iscove *et al.* in view of Keay. Applicants respectfully traverse this rejection.

Claim 1 as currently presented recites that the non-animal or plant-derived peptide is derived from a source selected from the group consisting of fungi, yeast, rice, potato, corn, and aloe vera. As noted above, neither Iscove *et al.* nor Keay discloses or suggests the use of non-animal or plant-derived peptides from these specific sources. Therefore, the claims are not unpatentable over Iscove *et al.* and Keay.

Applicants respectfully request this rejection be withdrawn.

E. U.S. Patent No. 5,122,469

Claims 1-7, 12, 13, 18-21, 26-28 and 33-38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,122,469. Applicants respectfully traverse this rejection.

The Examiner acknowledges that "the reference does not explicitly teach a single embodiment that uses all of these ingredients together." There is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time the invention was made. *See Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1995). Instead, what is needed is a reason, suggestion, or motivation in the prior art that would motivate one of ordinary skill to combine the cited references, and that would also suggest a reasonable

likelihood of success in making or using the claimed invention as a result of that combination. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). In the present case, the Examiner's burden has not been satisfied because the Examiner has not provided any reason, suggestion, or motivation in the prior art to combine the elements to arrive at the presently claimed invention.

In further distinction over the cited reference, claims 1 and 2, as presently claimed, recite that the non-animal or plant-derived peptide or lipid/fatty acid is derived from a source selected from the group consisting of fungi, yeast, rice, potato, corn, and aloe vera or derived from the group consisting of bacteria, fungi, yeast, rice, potato, corn, and aloe vera, respectively. U.S. Patent No. 5,122,469 does not disclose or suggest non-animal or plant-derived peptides, lipids or fatty acids from these recited sources. Hence, U.S. Patent No. 5,122,469 is seriously deficient as a primary reference upon which to base a *prima facie* case of obviousness. Therefore, the claims are not unpatentable over U.S. Patent No. 5,122,469.

Applicants respectfully request this rejection be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for

allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond

Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

Date: May 1, 2002

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

Version with markings to show changes made

In the specification, beginning at page 1, line 4:

This application [claims the benefit of U.S. Provisional Patent Application No. 60/028,197, filed October 10. 1996, and claims priority to U.S. Utility Patent Application Nos. 08/949,142, filed October 10, 1997, and 09/070,807, filed May 1, 1998,] is a continuation of U.S. Patent Application No. 09/302,953, filed April 30, 1999, now abandoned, which is a continuation-in-part of U.S. Patent Application No. 09/070,807, filed May 1, 1998, now abandoned, which is a continuation-in-part of U.S. Patent Application No. 08/949,142, filed October 10, 1997, now U.S. Patent No. 6,103,529, which claims priority to U.S. Provisional Patent Application No. 60/028,197, filed October 10, 1996, the entire contents of all of which are incorporated by reference.

In the claims:

1. (Once Amended) A cell culture medium comprising at least one non-animal or plant-derived peptide, wherein said non-animal or plant-derived peptide is derived from the group consisting of fungi, yeast, rice, potato, corn, and aloe vera [with the proviso that said peptide is not derived from wheat], and wherein said medium is capable of supporting the cultivation of an animal cell in vitro.

2. (Once Amended) A cell culture medium comprising at least one non-animal derived or plant-derived lipid or at least one non-animal or plant-derived fatty acid, wherein said non-animal or plant-derived lipid or fatty acid is derived from the group consisting of bacteria, fungi, yeast, rice, potato, corn, and aloe vera, and wherein said medium is capable of supporting the cultivation of an animal cell in vitro.

6. (Once Amended) A cell culture medium obtained by combining at least one non-animal or plant-derived peptide together with an animal cell culture medium, wherein said non-animal or plant-derived peptide is derived from the group consisting of fungi, yeast, rice, potato, corn, and aloe vera, and wherein said medium is capable of supporting the cultivation of an animal cell in vitro.

7. (Once Amended) A cell culture medium obtained by combining at least one non-animal or plant-derived lipid or at least one non-animal or plant-derived fatty acid together with an animal cell culture medium, wherein said non-animal or plant-derived lipid or fatty acid is derived from the group consisting of bacteria, fungi, yeast, rice, potato, corn, and aloe vera, and wherein said medium is capable of supporting the cultivation of an animal cell in vitro.

8. (Once Amended) The cell culture medium of claim 2, wherein said lipid or fatty acid is selected from the group consisting of palmitate, stearate, [olcate] oleate, linoleate, lineolenate, arachidate, myristate, behenate, erucate, lignocerate, caprylate, caprate, laureate and palmitoleate, and combinations thereof.

9. (Once Amended) The cell culture medium of claim 7, wherein said lipid or fatty acid is selected from the group consisting of palmitate, stearate, [olcate] oleate, linoleate, lineolenate, arachidate, myristate, behenate, erucate, lignocerate, caprylate, caprate, laurate and palmitoleate, and combinations thereof.

26. (Once Amended) A kit for replacing one or more animal-derived ingredients in a cell culture medium, comprising at least one non-animal or plant-derived peptide, lipid, fatty acid, or combinations thereof wherein said non-animal or plant-derived peptide, lipid or fatty acid is derived from the group consisting of fungi, yeast, rice, potato, corn, and aloe vera.

30. (Once Amended) The cell culture medium of claim 8, wherein said lipid or fatty acid is selected from the [combination comprising] group consisting of myristate, caprylate, caprate, laurate, stearate, oleate, palmitate and linoleate.

32. (Once Amended) The cell culture medium of claim 9, wherein said lipid or fatty acid is selected from the [combination comprising] group consisting of myristate, caprylate, caprate, laurate, stearate, oleate, palmitate and linoleate.

33. (Once Amended) The cell culture medium of claim 1, wherein the non-animal or plant derived peptide is derived from [any one of] the group consisting of fungi, yeast, [bacteria, soy,] rice, potato, corn and aloe vera.

34. (Once Amended) The cell culture medium of claim 1, wherein the non-animal or plant derived peptide is derived from [any one of] the group consisting of yeast, [soy,] rice, potato, corn and aloe vera.

36. (Once Amended) The cell culture medium of claim [1] 2, wherein the non-animal or plant derived lipid or fatty acid is derived from [any one of] the group consisting of fungi, yeast, [bacteria, soy,] rice, potato, corn and aloe vera.

37. (Once Amended) The cell culture medium of claim [1] 2, wherein the non-animal or plant derived lipid or fatty acid is derived from [any one of] the group consisting of yeast, [soy,] rice, potato, corn and aloe vera.

38. (Once Amended) The cell culture medium of claim [1] 2, wherein the non-animal or plant derived lipid or fatty acid is derived from [any one of] the group consisting of rice, potato, corn and aloe vera.

Claims 39 and 40 have been added.